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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/016,403	12/10/2001	Leslie A. Holladay	011293-9028	4840
23510	7590	12/24/2003	EXAMINER	
MICHAEL BEST & FRIEDRICH, LLP ONE SOUTH PINCKNEY STREET P O BOX 1806 MADISON, WI 53701			STEADMAN, DAVID J	
			ART UNIT	PAPER NUMBER
			1652	

DATE MAILED: 12/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/016,403	HOLLADAY, LESLIE A.
<b>Examiner</b>	<b>Art Unit</b>	
David J Steadman	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

1)  Responsive to communication(s) filed on 11 September 2003.

2a)  This action is **FINAL**.                            2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### **Disposition of Claims**

4)  Claim(s) 1,2 and 4-27 is/are pending in the application.  
4a) Of the above claim(s) 5-16 is/are withdrawn from consideration.  
5)  Claim(s) \_\_\_\_\_ is/are allowed.  
6)  Claim(s) \_\_\_\_\_ is/are rejected.  
7)  Claim(s) \_\_\_\_\_ is/are objected to.  
8)  Claim(s) 1,2,4 and 17-27 are subject to restriction and/or election requirement.

## Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on \_\_\_\_\_ is/are: a)  accepted or b)  objected to by the Examiner.

    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

    Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)  The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. §§ 119 and 120**

12)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a)  All b)  Some \* c)  None of:  
1.  Certified copies of the priority documents have been received.  
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.

13)  Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a)  The translation of the foreign language provisional application has been received.

14)  Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

**Attachment(s)**

1)  Notice of References Cited (PTO-892) 4)  Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_  
2)  Notice of Draftsperson's Patent Drawing Review (PTO-948) 5)  Notice of Informal Patent Application (PTO-152)  
3)  Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_. 6)  Other: \_\_\_\_\_

## DETAILED ACTION

### *Status of the Application*

- [1] Claims 1-2 and 4-27 are pending in the application.
- [2] Applicants' amendment to the claims filed September 11, 2003, is acknowledged.
- [3] Applicants' amendment to the title of the specification filed September 11, 2003, is acknowledged.
- [4] Claims 5-16 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.
- [5] The instant Office action is a supplemental restriction requirement of the claims being examined on the merits (claims 1-2, 4, and 17-27). In view of applicants' addition of claims reciting specific pharmaceutical parent polypeptides (claims 19, 22, and 25), the instant Office action is deemed necessary in view of the patentably distinct methods as set forth below.

### *Election/Restrictions*

- [6] Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claim(s) 1-2, 4, and 17-21, drawn to a method for delivering a pharmaceutical polypeptide agent, by providing a synthetic analog of human granulocyte colony stimulating factor, classified in class 514, subclass 2.

- II. Claim(s) 1-2, 4, and 22-24, drawn to a method for delivering a pharmaceutical polypeptide agent, by providing a synthetic analog of human parathyroid hormone, classified in class 514, subclass 2.
- III. Claim(s) 1-2, 4, and 25-27, drawn to a method for delivering a pharmaceutical polypeptide agent, by providing a synthetic analog of human growth releasing hormone, classified in class 514, subclass 2.

- [7] The inventions are distinct, each from the other because:
- [8] The methods of Groups I-III are independent as they utilize different products, i.e., structurally and functionally distinct polypeptides.
- [9] MPEP § 803 sets forth two criteria for a proper restriction between patentably distinct inventions: (A) The inventions must be independent or distinct as claimed and (B) There must be a serious burden on the examiner. As shown above, each of the inventions of Groups I-III are independent or distinct, thus satisfying the first criterion for a proper restriction. MPEP § 803 additionally states that a serious burden on the examiner may be *prima facie* shown if the examiner shows by appropriate explanation either separate classification, separate status in the art, or a different field of search. In this case, as each group recites a different polypeptide having a distinct structure and function, a separate patent and non-patent literature and sequence search for each Group is required. Thus, co-examination of the inventions of Groups I-III would place a serious burden on the examiner.

***Conclusion***

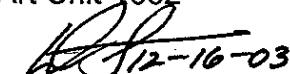
[10] Claim 1 will be examined to the extent the claim reads on the elected invention.

[11] Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

[12] Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Steadman, whose telephone number is (703) 308-3934. The Examiner can normally be reached Monday-Friday from 7:00 am to 5:00 pm. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (703) 308-3804. The FAX number for submission of official papers to Group 1600 is (703) 308-4242. Draft or informal FAX communications should be directed to (703) 746-5078. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Art Unit receptionist whose telephone number is (703) 308-0196.

David J. Steadman  
Patent Examiner  
Art Unit 1652



DAVID STEADMAN  
PATENT EXAMINER